

**Remarks**

**Status of Claims and Support for Claim Changes**

Claims 1-5 and 9, 11-14, and 18-19 are currently pending. Claims 6-7 and new claims 8, 10, 15-17, were previously cancelled. Claims 1-5 correspond with claims 1-5 as granted in U.S. Patent 6,348,069. Claims 9 and 11-14, and 18-20 are new claims, previously presented.

Claim 1 has been amended to specify a cell-matrix construct "in the shape of" rather than "for use as," a heart valve, or a "heart valve leaflet." Support can be found in the original patent at least at col. 7, lines 20-51, and examples 1 and 6. In claim 1, the previously amended "consisting of" has been replaced with "comprising." In claim 1, the matrix "is formed" was replaced with "consists." As discussed in the interview, this more clearly distinguishes prior art devices which include materials such as stainless steel or collagen, in combination with biodegradable synthetic polymers.

Part (b) of claim 1 was previously amended to specify that the cells are seeded "thereon" instead of "therein." Support can be found at col. 7, lines 20-25. Claim 1 was previously amended to specify that the matrix is a synthetic biocompatible chemically degradable polymers. See original issued patent US. 6,348,069, col. 4, to col. 5, line 43. Explicit support for synthetic is found at col. 4, line 6. Explicit support for chemically biodegradable is found at col. 4, lines 2-4. Explicit support for synthetic rather than natural polymers is found at col. 4, lines 33-39. Claim 1 was previously amended to clarify the claim language of (b). Claim 1 was previously

amended to more clearly define the structural features of the claimed matrix and method of making:

(1) the matrix is made of a synthetic biodegradable polymer which provides the biomechanical properties of the final construct (the heart valve or leaflet) until the seeded cells can lay down their own extracellular matrix (patent col. 3, lines 14-20; patent col. 5, lines 8-19) and

(2) the matrix is in the shape of the tissue engineered construct (i.e., heart valve or leaflet) so that the cells attach to and proliferate on it to the edges of the matrix (patent col. 3, lines 20-24; lines 62-66).

Claim 1 was previously amended to clarify that the cell-matrix must be in the shape of the tissue that it is to replace, in this case, a heart valve or heart valve leaflets. Support is found at col. 3, lines 21-24; 62-63; and 66-67 of the patent. Claim 1 was also previously amended to delete the product-by-process language, requiring a two step implantation process. This unnecessarily limited the claimed method. Claim 1 was also previously amended to clarify the claim language by replacing "selected from" with "consisting of." Claim 1 was previously amended to delete "a mixture of" with reference to cells seeded in the fibrous matrix. Support for the amendment can be found in the original patent at col. 6, lines 28-34.

New claim 9 was previously amended to delete some of the polymers.

Claim 2 was previously amended to delete "parenchymal cells," and to clarify the claim language.

Claim 3 was previously amended to replace “implanted at” with “transplanted to” to clarify the claim language. Support for the amendment can be found in the original patent at col. 7, lines 25-28.

Claim 4 was previously amended to refer to the matrix in the form of a heart valve leaflet. Support is found at col. 3, lines 66-67.

Claims 5 was previously amended to specify the valve is a heart valve. Support for the amendment can be found throughout the patent, such as example 1, col. 7-8.

Support for claim 9 is found at col. 4, line 2 to line 19.

Support for claim 11 is found at col. 3, line 57.

Support for claims 12 and 13 is found at col. 5, lines 50-67.

Support for claim 14 is found at col. 6, line 11.

Support for claims 18 and 19 is found in the patent at col. 7, lines 12-16. See also claim 3 where it is first implanted at a site in the host different from the final site of implantation.

Support for new claim 20, corresponding to claim 1 as originally issued, is drawn to a method of making cell-matrix constructs containing struts or support elements as described in the patent at col. 5, lines 31-43.

### **The Interview**

Applicants, the licensee, and the undersigned greatly appreciated the opportunity to interview this application with the examiner, supervisor David Isabella, and quality control specialist Greg Vidovich, on December 9, 2009, at the U.S. Patent Office. The extremely helpful

discussion with Mr. Isabella are also greatly appreciated. The claims have been amended as discussed at the interview and in the telephone calls with Mr. Isabella.

The term “formed” has been replaced with “consisting of”. As discussed, this more clearly distinguishes prior art devices which include materials such as stainless steel or collagen, in combination with biodegradable synthetic polymers.

The polymer has been amended to refer to synthetic biocompatible chemically degradable polymers. See original issued patent U.S. 6,348,069, col. 4, to col. 5, line 43. Explicit support for synthetic is found at col. 4, line 6. Explicit support for chemically biodegradable is found at col. 4, lines 2-4. Explicit support for synthetic rather than natural polymers is found at col. 4, lines 33-39. These amendments were made to distinguish any potential prior art using collagen or other polymers which are enzymatically degraded, not hydrolytically (chemically) degraded.

U.S.S.N. 10/782,750

Filed: February 19, 2004

**SUBSTITUTE AMENDMENT FOR**

**SUPPLEMENTAL AMENDMENT FILED JANUARY 13, 2010**

Claim 9 has been amended to refer to the preferred polymers.

Allowance of claims 1-5, 8, 11-14, and 18-20 is earnestly solicited.

Respectfully submitted,

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Date: February 10, 2010

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